## Remarks

## Rejection Under 35 U.S.C. § 102(b)

The Final Office Action maintains the rejection of claims 1 and 5-9 under 35 U.S.C. § 102(b) as anticipated by Yuasa. Applicants respectfully traverse the rejection.

A reference cited under 35 U.S.C. § 102 must expressly or inherently describe each element set forth in the rejected claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Independent claim 1 recites, *inter alia*, a step of "identifying the test compound as a candidate therapeutic agent useful in the treatment of a disease selected from the group consisting of disorders of the peripheral and central nervous system, cardiovascular diseases, cancer, liver disease, and genitourinary disease if the test compound binds to said PDE11A polypeptide." Yuasa does not disclose this step. The Examiner points to page 31469, right column, 2<sup>nd</sup> full paragraph of Yuasa contends that Yuasa teaches that "each PDE plays a distinct physiological role in different tissues and cells and may be valuable pharmacological targets." This is merely a generic teaching that does not expressly or inherently link PDE11A to any of the disorders recited in independent claim 1. Thus, Yuasa does not expressly anticipate independent claim 1.

Nor does Yuasa inherently anticipate claim 1. To establish inherency, extrinsic evidence "must make clear that the missing descriptive matter is <u>necessarily</u> present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 U.S.P.Q.2d 1746, 1759 (Fed. Cir. 1991) (emphasis added). The Examiner points to page 31478, right column, lines 1-4, where Yuasa teaches that "[t]he PDE inhibitors, 3-isobutyl-1-methylxanthine and papaverine, also initiate

<sup>&</sup>lt;sup>1</sup> Yuasa et al., J. Biol. Chem. 275, 31469-79, 2000.

morphologic differentiation in human prostate cancer cells and inhibit the proliferation and invasive potential of the cells." In fact, the cited portion of Yuasa teaches that "[i]n prostate, PDEs have been little studied" and that the PDE inhibitor studies and other reports "suggest that the involvement of a cAMP and cGMP PDE, PDE11A, in controlling prostate or testis functions is plausible." Paragraph bridging the left and right columns on page 31478. This is not an inherent anticipation of the claimed method.

Yuasa does not expressly or inherently anticipate claim 1 or dependent claims 5-9. Please withdraw the rejection.

## Rejection Under 35 U.S.C. § 103(a)

Claims 1 and 4-11 are rejected under 35 U.S.C. § 103(a) as obvious over Yuasa in view of Lanfear.<sup>2</sup> Applicants respectfully traverse the rejection.

The U.S. Patent and Trademark Office bears the initial burden of establishing a *prima* facie case of obviousness. The *prima facie* case requires three elements:

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Manual of Patent Examining Procedure, 8<sup>th</sup> ed., § 2142. As explained above, Yuasa does not teach or suggest the third step of claim 1. Lanfear also does not teach or suggest this step. Claims 1 and 4-11 are therefore not *prima facie* obvious over the cited combination.

Please withdraw the rejection.

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<sup>&</sup>lt;sup>2</sup> Lanfear *et al.*, US 2002/0115176.

Respectfully submitted, BANNER & WITCOFF, LTD.

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Date: May 6, 2007

Customer Number: 22907

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